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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,631	12/05/2003	John F. Shanley	032304-088	1114

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EXAMINER

BLANCO, JAVIER G

ART UNIT PAPER NUMBER

3738

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/729,631

Applicant(s)

SHANLEY ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 49-51, 53, 56-78, and 81-86 is/are pending in the application.
- 4a) Of the above claim(s) 67-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-51, 53, 56-62, 74-78 and 81-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicants' cancellation of claims 52, 54, 55, 63-66, 79, and 80 in the reply filed on February 7, 2005 is acknowledged.
2. Applicants' addition of claims 84-86 in the reply filed on February 7, 2005 is acknowledged.
3. Applicants' amendment of claims 49, 53, 59, and 74 in the reply filed on February 7, 2005 is acknowledged.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 49-51, 53, 56-62, 74-78, and 81-86 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Santini, Jr. et al. (US 6,656,162; cited in Applicants' IDS).

As seen in Figures 1, 2A-2E, 9A, and 9C, Santini, Jr. et al. disclose an expandable medical device comprising (i) a substantially cylindrical expandable medical device formed of a plurality of struts (see Figures 9A and 9C; see column 10, lines 44-67; column 14, line 63 to column 15, line 23), (ii) a plurality of openings (i.e., reservoirs) in the plurality of struts (see Figures 9A and 9C; see column 10, lines 44-67; column 14, line 63 to column 15, line 23), and

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(iii) a plurality of beneficial agent layers (i.e., an anti-proliferative, or, an anti-inflammatory, or, a protein drug: either in “pure form” or embedded in a biodegradable polymeric matrix) formed in the openings, wherein the plurality of beneficial agent layers (see column 5, lines 30-33) include a first active agent arranged for delivery according to a first release profile (e.g., Figure 2d, agent 540a; see column 4, lines 33-62; column 5, lines 20-37) and a second active agent arranged for delivery according to a second release profile (e.g., Figure 2d, agent 540b; see column 4, lines 33-62; column 5, lines 20-37). A barrier layer (reservoir cap and/or backing plate) is formed within the openings to block or retard delivery of the first and second active agents to the luminal side of the device body (see entire document).

### *Response to Arguments*

6. Applicant's arguments filed February 7, 2005 have been fully considered but they are not persuasive.

Applicants argue: (i) “A stent configuration with two drugs of Santini cannot be formed into the struts of a stent because the substrate stacking methods of forming the chips described in Santini are not useable on a stent” (see Remarks at page 8, lines 25-27); and (ii) “At most, Santini possibly teaches the attachment of a drug chip to the inside surface of a stent. Santini clearly does not teach two active agents with openings in the stent struts” (see Remarks at page 9, lines 2-4). Examiner respectfully disagrees. Santini ‘162 clearly disclose at column 15, lines 16-23 “*stents can be designed and fabricated to have drug reservoirs and caps as part of the stent itself, that is, not as a separate microchip device, but rather as part of a monolithic stent device. It is understood that both systemic and local delivery of any drug is possible using the*

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*microchip technology in combination with stents*". Said microchip technology includes any of the embodiments shown in Figures 2A-2E. It is noted that Applicants did not offer evidence on how "the substrate stacking methods of forming the chips described in Santini are not useable on a stent". Santini '162 further teaches the incorporation of several layers of a release system (a release system includes a drug(s) in pure form, or, a drug(s) in a polymeric matrix; see column 4, line 64 to column 5, line 27) into a single reservoir (see column 5, lines 30-33). An example of a single reservoir is shown in Figure 2A.

### *Conclusion*

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. This application contains claims 67-73 drawn to an invention nonelected without traverse in the Office Action mailed on November 4, 2004. A complete reply to the final rejection must

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include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

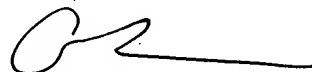
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



May 11, 2005



**CORRINE McDERMOTT**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER**